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Express Mail No. EU531587457US

TUL2AUSA

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application of

M. Philipp

Appln. No. 09/445,803

Filed: December 13, 1999

For: SURFACE ANTIGENS AND PROTEINS  
USEFUL IN COMPOSITIONS FOR THE  
DIAGNOSIS AND PREVENTION OF  
LYME DISEASE

Commissioner for Patents  
Washington, DC 20231

) Group Art Unit: 1645

) Examiner: R. Swartz

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DEC 18 2002  
TECH CENTER 1600/2900

**DECLARATION OF BIOLOGICAL CULTURE DEPOSIT AND  
CERTIFICATE UNDER 37 CFR §3.73(b)**

Sir:

I, J. Cale Lennon, III, Ph.D., Associate Director, Office of Technology  
Development, of Tulane University, hereby declare:

1. That I have been authorized to act on behalf of the assignee of the present application, i.e. The Administrators of the Tulane Educational Fund.
2. That the following culture referred to in the specification of this application was deposited on June 27, 1997, prior to the filing of the above-identified patent application and the priority US Provisional Patent Application No. 60/051,271:

Fragment 7-1 from *Borrelia garinii* strain IP90

98478

Strain

Accession Number

3. That the following cultures referred to in the specification of this application were deposited on June 10, 1998, prior to the filing of the above-identified patent application and during the pendency of the priority US Provisional Patent Application No. 60/051,271:

<u>Fragment 1-1 from <i>Borrelia garinii</i> strain IP90</u>	<u>98768</u>
<u>Fragment 3-1 from <i>Borrelia garinii</i> strain IP90</u>	<u>98769</u>
<u>Fragment 6-1 from <i>Borrelia garinii</i> strain IP90</u>	<u>98770</u>
<u>Fragment 9-1 from <i>Borrelia garinii</i> strain IP90</u>	<u>98771</u>
<u>Fragment 12-1 from <i>Borrelia garinii</i> strain IP90</u>	<u>98772</u>
Strains	Accession Numbers

4. That the name and address of the depository is:

American Type Culture Collection  
10801 University Boulevard  
Manassas, VA 20110-2209  
(703) 365-2700

5. That statements that the cultures deposited with the above named depository were viable and were capable of reproduction on the dates of deposit are attached. Such statements are executed by the depository.

6. That, with respect to the permanence of the cultures' deposit:

(a) the depository is an official depository and these deposits have been made under the terms of the Budapest Treaty for the above deposited cultures.

(b) the depository affords permanence of the deposits for at least 30 years or at least 5 years after the most recent storage request, whichever is longest.

(c) evidence that permanent availability of the cell lines is assured is provided in the form of the attached copies of the contracts with the above-mentioned depository with respect to the deposited cultures.

I affirm that should the cell lines mutate, become nonviable or be inadvertently destroyed, applicant will replace such cultures for at least 30 years from the date of the original deposits, or at least 5 years from the date of the most recent request for release of a sample or for the life of any patent issued on the above-mentioned application, whichever period is longer.

7. That, with respect to availability of the cultures, I affirm that the deposits have been made under conditions of assurance of (a) ready accessibility thereto by the public if a patent is granted and (b) that access to the cultures will be available during pendency of the patent application to one determined by the Commissioner to be entitled thereto under 37 CFR § 1.14 and 35 USC § 122. I affirm that all restrictions imposed by the depositor on the availability to the public of the deposited materials will be irrevocably removed upon the granting of a patent.

8. Evidence of the accessibility of the cultures as set forth above is provided in the form of the attached copies of the contracts with the above mentioned depository with respect to the deposited cultures.

9. That I hereby further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

10. As required under 37 CFR 3.73(b), I declare that the evidentiary document relating to the ownership of the above-identified application No. 09/445,803 and the invention claimed therein has been reviewed, and consists of the assignment of the above-identified US patent Application No. 09/445,803. The assignment for US patent Provisional Application No. 60/051,271 was executed on July 25, 2000 and forwarded to the United States Patent and Trademark Office for recordation on November 20, 2002. A copy of the assignment and the forwarding papers are submitted herewith. A copy of a new assignment for US patent Application No. 09/445,803 is attached hereto. I certify that, to the best of my knowledge and belief, title to US Patent Application No. 09/445,803 is solely in the assignee, The Administrators of the Tulane Educational Fund.

The Administrators of the Tulane Educational Fund

Date: December 4, 2002

By: J. Cale Lennon III

J. Cale Lennon, III, Ph.D.

Associate Director

Office of Technology Development SL-13

Tulane University Health Sciences Center

1430 Tulane Avenue

New Orleans, LA 70112-2699



# American Type Culture Collection

12301 Parklawn Drive • Rockville, MD 20852 USA • Telephone: 301-231-5519 or 231-5532 • FAX: 301-816-4366

BUDAPEST TREATY ON THE INTERNATIONAL RECOGNITION OF  
THE DEPOSIT OF MICROORGANISMS FOR THE PURPOSES OF PATENT PROCEDURE

## INTERNATIONAL FORM

RECEIPT IN THE CASE OF AN ORIGINAL DEPOSIT ISSUED PURSUANT TO RULE 7.3  
AND VIABILITY STATEMENT ISSUED PURSUANT TO RULE 10.2



To: (Name and Address of Depositor or Attorney)

Tulane University Primate Research Center  
Attn: Mario T. Philipp, Ph.D.  
18703 Three Rivers Road  
Covington, LA 70433

Deposited on Behalf of: The Administrators of the Tulane Education Fund

Identification Reference by Depositor: ATCC Designation

*Escherichia coli* SURE 7-1 IP90 98478

The deposit was accompanied by: ☐ a scientific description ☒ a proposed taxonomic description indicated above.

The deposit was received June 27, 1997 by this International Depository Authority and has been accepted.

AT YOUR REQUEST: ☒ We will inform you of requests for the strain for 30 years.

The strain will be made available if a patent office signatory to the Budapest Treaty certifies one's right to receive, or if a U.S. Patent is issued citing the strain, and ATCC is instructed by the United States Patent & Trademark Office or the depositor to release said strain.

If the culture should die or be destroyed during the effective term of the deposit, it shall be your responsibility to replace it with living culture of the same.

The strain will be maintained for a period of at least 30 years from date of deposit, or five years after the most recent request for a sample, whichever is longer. The United States and many other countries are signatory to the Budapest Treaty.

The viability of the culture cited above was tested July 1, 1997. On that date, the culture was viable.

International Depository Authority: American Type Culture Collection, Rockville, Md. 20852 USA

Signature of person having authority to represent ATCC:

Barbara M. Hailey  
Barbara M. Hailey, Administrator, Patent Depository

Date: July 1, 1997

cc: Mary E. Bak, Esq. (Ref. Docket TUL2USA)

# ATCC

10801 University Blvd • Manassas, VA 20110-2209 • Telephone: 703-365-2700 • FAX: 703-

BUDAPEST TREATY ON THE INTERNATIONAL RECOGNITION OF  
THE DEPOSIT OF MICROORGANISMS FOR THE PURPOSES OF PATENT PROCEDURE

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Attn: Mario T. Philipp, Ph.D.  
18073 Three Rivers Road  
Covington, LA 70433

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DEC 18 2002

TECH CENTER 1600/2900

Deposited on Behalf of: The Administrators of the Tuland Education Fund

Identification Reference by Depositor:

Fragment 1-1 from *Borrelia garinii* strain IP90  
Fragment 3-1 from *Borrelia garinii* strain IP90  
Fragment 6-1 from *Borrelia garinii* strain IP90  
Fragment 9-1 from *Borrelia garinii* strain IP90  
Fragment 12-1 from *Borrelia garinii* strain IP90

ATCC Designation

98768  
98769  
98770  
98771  
98772

The deposits were accompanied by:      a scientific description      a proposed taxonomic description indicated above. The deposits were received June 11, 1998 by this International Depository Authority and have been accepted.

AT YOUR REQUEST: X We will inform you of requests for the strains for 30 years.

The strains will be made available if a patent office signatory to the Budapest Treaty certifies one's right to receive, or if a U.S. Patent is issued citing the strains, and ATCC is instructed by the United States Patent & Trademark Office or the depositor to release said strains.

If the cultures should die or be destroyed during the effective term of the deposit, it shall be your responsibility to replace them with living cultures of the same.

The strains will be maintained for a period of at least 30 years from date of deposit, or five years after the most recent request for a sample, whichever is longer. The United States and many other countries are signatory to the Budapest Treaty.

The viability of the cultures cited above was tested June 26, 1998. On that date, the cultures were viable.

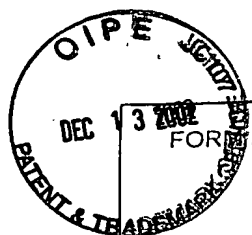
International Depository Authority: American Type Culture Collection, Manassas, VA 20110-2209 USA.

Signature of person having authority to represent ATCC:

Barbara M. Hailey  
Barbara M. Hailey, Administrator, Patent Depository

Date: July 1, 1998

cc: Mary E. Bak (Ref. Docket TUL2USA)



FOR USPTO-1595(modified)

RECORDATION FORM COVER SHEET  
PATENTS ONLYU.S. Department of Commerce  
Patent and Trademark Office

To the Honorable Director of the USPTO: Please record the attached original documents or copy thereof

## 1. Name of conveying party(ies):

Mario T. Philipp

Additional name(s) of conveying party(ies)  
attached?☐ yes ☒ no

## 3. Nature of Conveyance:

☒ Assignment ☐ Merger  
☐ Security Agreement ☐ Change of Name  
☐ Other \_\_\_\_\_Effective Date: July 25, 2000

## 2. Name and address of receiving party(ies)

Name: The Administrators of the Tulane Educational Fund

Internal Address: \_\_\_\_\_

Street Address: 1430 Tulane AvenueCity: New Orleans State: Louisiana Zip: 70112-2699Additional name(s) & address(es) attached? ☐ yes ☒ no

## 4. Application number(s) or patent number(s):

If this document is being filed with a new application, the execution date of the application is: \_\_\_\_\_

A. Patent Application No.(s)

60/051,271

B. Patent No.(s)

Additional numbers attached: ☐ yes ☒ no5. Name and address of party to whom  
correspondence concerning document should be  
mailed:Name: Mary E. Bak, EsquireHowson and Howson

Internal Address: \_\_\_\_\_

Street Address: Spring House Corporate Center,Box 457City: Spring House State: PA Zip: 194776. Total number of applications and  
Patents involved:..... 17. Total fee (37 CFR 3.41).....\$ 40.00☒ Enclosed☒ Authorized to be charged to deposit account

## 8. Deposit account number:

08-3040(Attach duplicate copy of this page if paying by deposit  
account)

Do not use this space

## 9. Statement and signature

To the best of my knowledge and belief, the foregoing information is true and correct and any attached copy is a  
true copy of the original document.Mary E. Bak

Name of Person Signing

Mary E. Bak  
SignatureNovember 20, 2002

Date

Total number of pages, including cover sheet, attachments, and document: 3Mail documents to be recorded with required coversheet information to:  
Director of the USPTO, Box Assignments  
Washington, DC 20231



## ASSIGNMENT

WHEREAS, Mario T. Philipp, hereinafter referred to as ASSIGNOR, has invented and is the owner of an invention entitled SURFACE ANTIGENS AND PROTEINS USEFUL IN COMPOSITIONS FOR THE DIAGNOSIS AND PREVENTION OF LYME DISEASE, said invention being fully set forth and described in the provisional application for Letters Patent of the United States filed on June 30, 1997 and assigned Serial No.60/051,271 prepared in connection with said invention, and

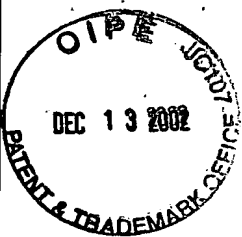
WHEREAS, The Administrators of the Tulane Educational Fund, a corporation organized and existing under and by virtue of the laws of the state of Louisiana and engaged in business at 1430 Tulane Avenue, New Orleans, Louisiana 70112-2699 hereinafter referred to as ASSIGNEE, is desirous of acquiring the said invention and any and all applications for Letters Patent and any and all Letters Patent of the United States and foreign countries which may be issued therefor;

NOW, THEREFORE, THIS IS TO WITNESS that in consideration of the sum of One Dollar (\$1.00) paid to ASSIGNOR by ASSIGNEE, the receipt of which is hereby acknowledged, and for other good and valuable consideration, ASSIGNOR has sold, assigned and set over, and hereby does sell, assign and set over, unto ASSIGNEE, its successors and assigns, the entire right, title and interest for, to and within the United States and all foreign countries, in and to the aforesaid invention and in and to any application for Letters Patent which assignee at its expense may cause to be filed in the United States, under an international treaty, or in any foreign country, and in any United States or foreign patent which may be granted on said invention, including any extensions, divisions, reissues, continuations or continuations-in-part.

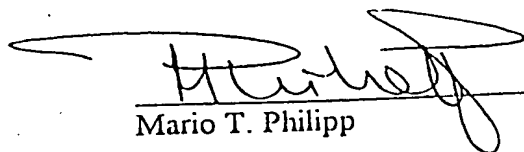
And ASSIGNOR hereby authorizes and requests the Director of the US Patents and Trademarks to issue any and all Letters Patent of the United States to ASSIGNEE, its successors and assigns, as the owner of all right, title and interest therein.

And for said consideration, it is hereby covenanted and agreed that at the request and expense of ASSIGNEE, its successors and assigns, ASSIGNOR will execute any further papers and do such other acts and things as may be necessary and proper to procure Letters Patent for said invention in the United States and in such foreign countries as ASSIGNEE, its successors and assigns may elect, and vest the full title thereto in ASSIGNEE, its successors and assigns.

And ASSIGNOR hereby authorizes and directs its attorneys to insert, in the space provided below, the serial number and filing date of the aforesaid application for Letters Patent of the United States when the same shall have been made known to them by the United States Patent and Trademark Office.



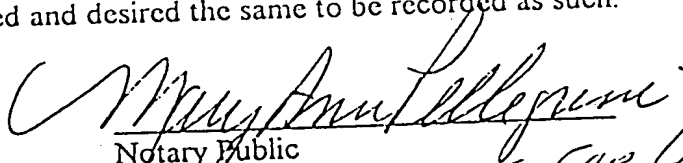
IN WITNESS WHEREOF, this assignment has been executed this 25<sup>th</sup> day of July 2000. This assignment is executed, on the above date and is to have effect nunc pro tunc as of June 30, 1997.

 (SEAL)  
Mario T. Philipp

NOTARIAL CERTIFICATE

State of Louisiana :  
County of St. Tammany ss. :

Before me, the undersigned, a notary public, in and for the county aforesaid, on this 26 day of July 2000, personally appeared Mario T. Philipp to me known to be the person described in and who executed the foregoing instrument and who acknowledged the execution of the same as a free act and deed and desired the same to be recorded as such.

  
Notary Public  
my commission is FOR LIFE



RECEIVED

DEC 18 2002

TECH CENTER 1600/2900

ASSIGNMENT

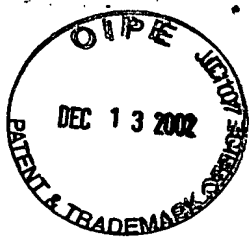
WHEREAS, Mario T. Philipp, hereinafter referred to as ASSIGNOR, has invented and is the owner of an invention entitled SURFACE ANTIGENS AND PROTEINS USEFUL IN COMPOSITIONS FOR THE DIAGNOSIS AND PREVENTION OF LYME DISEASE, said invention being fully set forth and described in the application for Letters Patent of the United States which has been prepared in connection with said invention, and which has been filed on December 13, 1999 and given Application Number 09/445,803.

WHEREAS, The Administrators of the Tulane Educational Fund, a corporation organized and existing under and by virtue of the laws of the State of Louisiana and engaged in business at 1430 Tulane Avenue, New Orleans, Louisiana 70112-2699, hereinafter referred to as ASSIGNEE, is desirous of acquiring the said invention and any and all applications for Letters Patent and any and all Letters Patent of the United States and foreign countries which may be issued therefor.

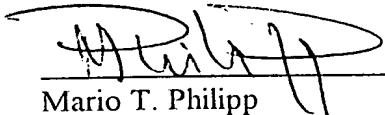
NOW, THEREFORE, THIS IS TO WITNESS that in consideration of the sum of One Dollar (\$1.00) paid to ASSIGNOR by ASSIGNEE, the receipt of which is hereby acknowledged, and for other good and valuable consideration, ASSIGNOR has sold, assigned and set over, and hereby does sell, assign and set over, unto ASSIGNEE, its successors and assigns, the entire right, title and interest for, to and within the United States and all foreign countries, in and to the aforesaid invention and in and to any application for Letters Patent which ASSIGNEE at its expense may cause to be filed in the United States, under an international treaty, or in any foreign country, and in any United States or foreign patent which may be granted on said invention, including any extensions, divisions, reissues, continuations or continuations-in-part.

And ASSIGNOR hereby authorizes and requests the Director of the USPTO to issue any and all Letters Patent of the United States to ASSIGNEE, its successors and assigns, as the owner of all right, title and interest therein.

And for said consideration, it is hereby covenanted and agreed that at the request and expense of ASSIGNEE, its successors and assigns, ASSIGNOR will execute any further papers and do such other acts and things as may be necessary and proper to procure Letters Patent for said invention in the United States and in such foreign countries as ASSIGNEE, its successors and assigns may elect, and vest the full title thereto in ASSIGNEE, its successors and assigns.



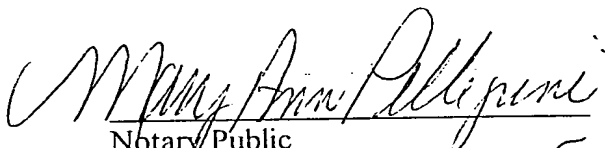
IN WITNESS WHEREOF, this assignment has been executed  
this 2nd day of December, 2002.

 (SEAL)  
Mario T. Philipp

NOTARIAL CERTIFICATE

State of LOUISIANA :  
County of ST TAMMANY : ss.  
:

Before me, the undersigned, a notary public, in and for the county  
aforesaid, on this 2nd day of DECEMBER, 2002, personally appeared Mario T.  
Philipp to me known to be the person described in and who executed the foregoing  
instrument and who acknowledged the execution of the same as a free act and deed  
and desired the same to be recorded as such.

  
Notary Public  
MY COMMISSION IS FOR LIFE